REMARKS/ARGUMENTS

Status of the Claims

Claims 53, 58-64, 67, 70, 71, 74, 77- 88, 91, and 93 to 100 were previously pending in the application. Claims 53 and 78 are amended. Claims 67, 77, and 91 are canceled herein without prejudice. After entry of these amendments. claims 53, 58-64, 70, 71, 74, 78- 88, and 93 to 100 will be pending.

Support for the amendments to the claims

Claims 53 and 78 are amended herein to set forth a particular embodiment wherein dendritic cells are used to present PSCA the protein or protein fragments to T cells in the context of MHC class I and II molecules. Support for this amendment can be found in lines 1 to 16 on page 61 of the original specification.

Accordingly, the Applicants believe the amendments to the claims add no new matter and respectfully request their entry.

First rejection under 35 U.S.C. §112, first paragraph

Claims 53, 58-64, 67, 70, 71, 74, 77-88, 91, and 93-100 stand rejected for allegedly failing to comply with the enablement requirement. To the extent that the rejection applies to the amended claim set, Applicants respectfully traverse the rejection.

In an earnest attempt to expedite prosecution and without acquiescing on the merits of the rejection, Applicants have amended independent claims 53 and 78 to set forth the embodiment wherein dendritic cells are used to present PSCA the protein or protein fragments to T cells in the context of MHC class I and II molecules.

As outlined in Applicant's previous response, submitted on October 11, 2007 and herein incorporated by reference, the existence of clinical trials strongly evidences that persons of ordinary skill in the art felt the art was reasonably predictable and ought to be so viewed by the Examiner. Indeed, the MPEP §2107.03 at 2100-35 right column provides:

> ... In order to determine a protocol for phase I testing, the first phase of clinical investigation, some credible rationale of how the drug might be effective or could be effective would be necessary. Thus, as a general rule, if an applicant has initiated human clinical trials for a therapeutic product or process, Office personnel should presume that the applicant has established that the subject matter of that trial is reasonably predictive of having the asserted therapeutic utility.

[underlining in the original].

Thomas-Kaskel et al. (already of record) have reported the results of a clinical trial using $PSCA_{14-22}$ and PSA peptide-loaded dendritic cells to vaccinate advanced prostate cancer patients (see. Thomas-Kaskel et al., Intl. J. Cancer 119:2428-2434 (2006), already of record). The study concludes:

> The experience from this trial argues that DC-based vaccination against PSCA in the dose range given seems worthwhile for further clinical testing as a vaccination antigen. However, immunosuppression is likely to prevent higher rates of immune responders unless active immunotherapy is being employed earlier in the course of the disease, for example in the setting of a ''PSA relapse'' after radical prostatectomy. The correlation of immune responses with superior overall survival, further supported by documented regression of lymph node metastasis or impressive subjective pain relief, suggests that tumor-specific cellular immunity may indeed provide clinical benefit in CaP, although the optimal time point and vaccination schedule need further clarification.

Considering the above, persons in the art are using the claimed invention successfully with no sign of undue experimentation. Thus, the claims are clearly enabled.

Accordingly, Applicants respectfully request that the above rejection be reconsidered and withdrawn.

Second and third rejections under 35 U.S.C. §112, first paragraph

Claims 53, 58-64, 67, 70, 71, 74, 77-88, 91, and 93-100 stand rejected for allegedly failing to comply with the written description and enablement requirements. To the extent that the rejection applies to the amended claim set, Applicants respectfully traverse the rejection.

In an earnest attempt to expedite prosecution and without acquiescing on the merits of the rejection, Applicants have amended independent claims 53 and 78 to recite a PSCA protein that is SEQ ID NO:2. As the amended claims are drawn to a single PSCA species, that of SEQ ID NO:2, which is clearly taught in the specification, Applicants submit that the specification provides an adequate written description and furthermore, that the claims are clearly enabled.

Accordingly, Applicants respectfully request that the above rejection be reconsidered and withdrawn.

Forth rejection under 35 U.S.C. §112, first paragraph

Claims 67 and 91 stand rejected for allegedly failing to comply with the written description requirement. In an earnest attempt to expedite prosecution and without acquiescing on the merits of the rejection, Applicants have herein canceled claims 67 and 91, rendering this rejection moot.

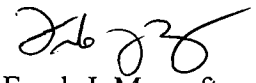
Accordingly, Applicants respectfully request that the above rejection be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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Attachments
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